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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
JOHNSON III, HENRY M	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 05/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/776,936	ALTSHULER ET AL.	
	Examiner	Art Unit	
	Henry M. Johnson, III	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *10 and 11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,12-15 and 17-34* is/are rejected.

7)☒ Claim(s) *9 and 16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 July 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All / b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *020705 020206*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Arguments

Applicant's arguments filed 3/31/2006 have been fully considered but they are not persuasive. Muller clearly is capable of irradiating more than one tissue type as the radiation is disclosed as being both between and through the bristles. Further, the device would radiate in multiple directions from the head when the optional reflective coating is not present (Col. 3:19-30), thus irradiating much of the interior of the oral cavity. Applicant's arguments regarding claim 15 are invalid as the limitations (no radiation except upon contact) in question are not in the claim.

Diffusing radiation is well known in the art, particularly when the target tissue is not a well defined point area. Diffusing optics, scattering of the beam and variations in fiber cladding are common and well known techniques for diffusing a treatment beam. The beam of Muller delivered between the bristles and through the bristles is inherently diffused as is the radiation through the non-coated head.

One skilled in the art would most certainly be motivated to look to similar devices for features like motion sensors and contact sensors, and include such if deemed desirable. Neither of the sensors is given any criticality by the applicant as a contact sensor is only mentioned cursorily in the specification and the motion sensor, not at all.

One skilled in the art of using energy producing devices, most certainly is cognizant of the potential issue with heat generated by such devices. Heat sinks are well known in the related arts and it would be obvious to look to others to determine a best mode to remove heat. None of the techniques disclosed is unique.

Neuberger et al. disclose a delivery port. The use of such port is intended use and not considered in evaluating the structure.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 and 12-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-20 of copending Application No. 10/776686. Although the conflicting claims are not identical, they are not patentably distinct from each other because the are an obvious change in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-4, 12-18 and 20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-12 and 14-20 of copending Application No. 10/776687. Although the conflicting claims are not identical, they are not patentably distinct from each other because the are an obvious change in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-5, 8-9, 14, 16-18 and 20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-23 of copending Application No. 10/777022. Although the conflicting claims are not identical, they are not patentably distinct from each other because the are an obvious change in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: radiation controlled by a motion sensor signal is not in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 14 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is indefinite as worded in that the distinction between radiation source and emitter is not clear, nor is the structural relationship between these elements.

Claim 14 is indefinite for being dependent on a withdrawn claim.

Claim 29 is indefinite as the power density to penetrate the mucosal lining is not defined or disclosed. If it is considered well known by one in the art, then it is obvious. Further, the ability to penetrate tissue is wavelength dependent, making the power dependent on this variable as well.

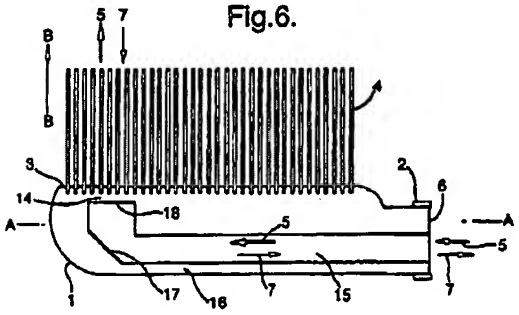
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 7-8, 12-13, 15, 17, 19, 23, 29-30, 32 and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,862,771 to Muller. Muller teaches a toothbrush with a head with bristles and a radiation source in a handle. The location in the handle is disclosed as convenient if the toothbrush is an electrical toothbrush, i.e. having electrical drive means to move the cleaning bristles in a tooth cleaning operation. The electric drive is interpreted as a vibrating mechanism. The radiation is directed in a direction parallel to the bristles either between the bristles or through the optically transparent bristles, thus teaching a plurality of emitters (Fig. 6) and radiation of both tissue in contact with the bristles and other tissue. A reflecting surface directs the radiation to the bristles (Fig. 6, # 17). Along with the radiation source in the handle, a detector is disclosed for sensing reflected radiation. This detector is interpreted as a diagnostic sensor (Col. 2, lines 38-65). The head is disclosed as optionally having a partial or whole coating to reflect the radiation into the head and bristles and to prevent loss of radiation, thereby indicating radiation indiscriminately (multiple directions) from the head in its absence (Col. 3:19-30). Both the radiation scattered by the bristles and radiated through the head is interpreted as diffused. The apparatus is clearly capable of radiating any area within an oral cavity. The

Fig.6.



radiation source may be a light emitting diode (LED) of known type and filters and mirrors are disclosed in the optical path. The detection means and an appropriate power supply, electronic processing devices, and means to signal the presence and/or absence of biological deposits on a tooth surface may conveniently be provided within the handle of the toothbrush (Col. 8:35-50). A lens may be used in the optical path (Col. 12:38) and this is interpreted as a diffuser as lenses may diverge a beam, effectively diffusing the beam. The bristles have a core made of a transparent plastic material, surrounded by a sheath also of a transparent plastic material with a lower refractive index than that of the core. Alternatively the sheath may be thin coating of a shiny metal, e.g. 2-3 microns thick (col. 13:12-17). The head is disclosed as being detachable (Col. 8:55).

Claims 1-8, 13, 17-19 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,902,397 to Farrell et al. Farrell et al. teach a device for delivery of light to the oral cavity. The device may be a toothbrush having tufts of bristles mounted to the top surface of the head of the toothbrush at its distal or working end. The placement of the light source may be near the center of the top surface of the head just below, just above, or at its surface and surrounded by the field of bristle tufts, just below, just above, or at the top surface of the head but outside of the field of tufts, at any edge of the head, or within the head directly below the proximal tips of the bristles, etc. (Col. 2:50-58). The light may also be in the handle with the light scattered in all directions including parallel to the bristles. Other scattering provides light to other areas of the mouth (Col. 5:7-26). The scattering is interpreted as diffusing of the light. Two LEDs may be located directed under the bristles in a manner to maximize transmission through as well as along the bristles (Col. 7:20-25) thereby disclosing optically transmissive bristles. The LEDs provide two sources and the tufts of bristles proved multiple emitters. The light source may be a mercury-xenon bulb (Col. 11:20) inherently providing multiple spectral

band of radiation. A detachable head is disclosed (Fig. 3B). Farrell et al. teaches a sensor for activation of the light source (Col. 5:47-50). Farrell et al. also discloses an embodiment with a port for delivery of liquid such as a photocatalytic dye (Col. 9:63).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,862,771 to Muller. Muller does not disclose the etching of a core cladding to diffuse the radiation. The practice of etching or otherwise modifying the refraction characteristics of a cladding to achieve a desired radiation effect or fluence is well known. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the etching technique to diffuse the radiation.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,902,397 to Farrell et al. as applied to claim 1 above, and further in view of U.S. Patent

6044,514 to Kaneda et al. Farrell et al. are discussed above, but do not teach bristle shape. Kaneda et al. disclose tapered bristles for a toothbrush. Various shapes of bristles are common on toothbrushes and it would have been obvious to one skilled in the art to use the tapered bristles as taught by Kaneda et al. in the invention of Farrell et al. to provide flexibility and ability to reach different areas.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,902,397 to Farrell et al. as applied to claim 1 above, and further in view of U.S. Patent 6,129,723 to Anderson et al. Farrell et al. are discussed above, but do not teach selective refraction. Anderson et al. teach total internal reflection based on the shape of an optically transmissive element and the differences of the indexes of refraction. It would have been obvious to one skilled in the art to use the concept of total internal reflection as taught by Anderson et al. in the invention of Farrell et al. to control the irradiation from the bristles and Farrell et al. clearly recognizes concerns in the regard by suggesting sensors in the device.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,902,397 to Farrell et al. as applied to claim 1 above, and further in view of U.S. Patent 6,029,303 to Dewan. Farrell et al. as discussed above disclose a sensor, but do not teach the use of a motion sensor. Dewan teaches an electronic toothbrush with a handle, head, and bristles with a motion detector that activates a light or audio signal. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the motion detector as taught by Dewan in the device of Farrell et al. to control or restrict the radiation to when the unit is in use.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,902,397 to Farrell et al. as applied to claim 1 above, and further in view of U.S. Patent 5,133,120 to Sakuma. Farrell et al. as discussed above teach a sensor, but do not teach the

use of a contact sensor. Sakuma discloses an electronic toothbrush with a handle, head and bristles and a circuit that energizes a radiation device when the bristles contact the teeth, thus sensing contact and completing the circuit via the body of the user. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the contact sensor as taught by Sakuma in the device of Farrell et al. to activate the device when in the preferred use position, in contact with the oral tissue.

Claims 24, 26, 28 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,862,771 to Muller as applied to claim 1 above, and further in view of U.S. Patent 4,333,197 to Kuris. Muller is discussed above, but does not teach the use of heat sinks or ultrasonics, although the handle of Muller would inherently transfer heat from the radiation source in the handle to the rest of the device body and head because virtually all materials have some heat transfer capacity. Kuris teaches an ultrasonic toothbrush with a handle, head and bristles driven by ultrasonic frequencies (abstract). The handle is designed to remove the heat produces by the ultrasonic generator (Col. 4:28-31). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the ultrasonic generator and heat removal techniques as taught by Kuris in the device of Muller to complement the hygienic process within an oral cavity. Generation and removal of heat is well known to one of skill in the art and would motivate one to look to existing means for removal of heat if deemed necessary.

Claims 25 and 27 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,862,771 to Muller in view of U.S. Patent 4,333,197 to Kuris as applied to claim 24 above, and further in view of U.S. Patent 6,350,276 to Knowlton. Muller and Kuris are both discussed above, but do not disclose cooling using fluids or phase changing substances. Knowlton discloses an apparatus for treating tissue using energy sources that may be light (Col. 7:55-56). Figure 5, from a cross-referenced (and incorporated) Knowlton patent (6,425,912),

teaches energy sources (Fig. 5, # 18) that conform to the skin. Knowlton teaches cooling of the sources and tissue using a liquid (Fig. 2B, # 15) that can be in a liquid or gaseous state, or may exist in two or more phases and may undergo a phase change as part of its cooling function (Col. 5, lines 29-35), such as melting or evaporation (whereby heat is absorbed by the fluid as a latent heat of fusion or evaporation). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the cooling methodologies as taught by Knowlton et al. in the invention of Muller as modified by Kuris if the radiation sources require cooling as the fluid and phase change methods are common and known.

Allowable Subject Matter

Claims 9 and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Henry M. Johnson, III
Primary Examiner
Art Unit 3739